REMARKS/ARGUMENTS

Claims 2-4, 8-13 and 16 are active.

Claims 2 and 10-11 have been amended to incorporate the limitations of Claims 6, 7, 14 and 15 with respect to the fructosyl valine or fructosyl valylhistidine. Support for the correlating is found in paragraph [0028] and the Examples.

Claims 3, 4, 7-8, 9, 12, 13, and 16 are amended for clarity and to make those claims consistent with the changes in Claims 2, 10 and 11.

No new matter is added.

The claims have also been amended to address the claim objections noted at pages 3-4 of the Action, to remove improper multiple dependencies, and for clarity. That is, the method steps of treating a sample with a protease, reacting the fructosyl valine or fructosyl valylhistidine with a-n enzyme, measuring the product and correlating the measurement to the level of glycated protein in the sample is provided in Claim 2. Claims 10 and 11 also define acting (A) to (C) and measuring and correlating the product to the goal of the method as set forth in the preamble. Accordingly, withdrawal of the rejection applied under 35 USC 112, second paragraph is requested.

The specification is amended at page 18 to amend the description for TRITON® X-100 as requested in the Action at pages 2-3. TRITON® X-100 is a known nonionic surfactant which has a hydrophilic polyethylene oxide group (on average it has 9.5 ethylene oxide units) and a hydrocarbon lipophilic or hydrophobic group. The hydrocarbon group is a 4-(1,1,3,3-tetramethylbutyl)-phenyl group.

The specification is also amended to provide the priority information as requested at page 3 of the Action.

No new matter is added.

A reformatted IDS is submitted as requested at page 4 of the Action.

The rejection of Claims 1-2 under 35 USC 102(b) citing Watanabe is inapplicable as claim 1 is cancelled and Watanabe et al. does not disclose treating the sample with a protease to release free fructosyl valine or fructosyl valylhistidine or reacting an enzyme for assaying fructosyl valine or fructosyl valylhistidine with the released fructosyl valine or fructosyl valylhistidine.

Previously known enzymes for assaying glycated protein, such as fructosyl amino acid oxidase and fructosyl peptide oxidase are known to react specifically with a glycated amino acid or peptide at pH 8.0 (paragraph [0005]). The preferable target of the enzymes is fructosyl valine or fructosyl valylhistidine, however, they also have some reactivity with fructosyl lysine (paragraph [0006]). The reactivity of the enzymes to fructosyl lysine is relatively low but problematic in an assay of glycated protein because samples of interest often have a compound containing fructosyl lysine (fructosyl lysine compound). For example, representative glycated proteins of interest, such as glycated hemoglobin, have many lysine residues (e.g., 44 ϵ-fructosyl lysine residues in the case of hemoglobin) as well as targeted α-fructosyl valine residue. Therefore, conventional assays of glycated protein may lead to errors due to the fructosyl lysine present in a sample.

The present invention has solved the problem of the conventional assays by reacting the enzyme at a pH of 4.0 to 7.0 with fructosyl valine or fructosyl valylhistidine released from the glycated protein and by measuring the product of the reacting at a pH of 4.0 to 7.0. The present inventors have found that the reactivity of the enzyme for assaying glycated protein with fructosyl lysine is decreased under the pH condition thereby the adverse effect of a fructosyl lysine compound on measuring a glycated protein is reduced. Prior to the present invention, nobody has found the effect of pH condition on the reactivity of the enzyme to

fructosyl lysine nor reported to modify pH condition in order to reduce the adverse effect of fructosyl lysine on the assay of glycated protein.

Therefore, the pH ranges coupled with the enzyme treatment for assaying fructosyl valine or fructosyl valylhistidine as defined in the claims reduce the effect a fructosyl lysine compound in assay of a glycated protein. Such is neither disclosed nor suggested by Watanabe and as such withdrawal of the rejection is requested.

Upon consideration of the amendments and discussion submitted in this paper, a Notice of Allowance for all pending claims is also requested.

Respectfully submitted,

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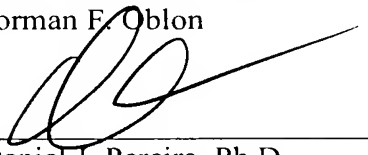

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